SEP 0 9 2008

K081744

2.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	OptiMedica Corporation
TRADE NAME:	PASCAL Synthesis™ Delivery System
COMMON NAME:	Scanning Photocoagulator Delivery System
DEVICE CLASSIFICATION	GEX 21 CFR 878.4810 Laser instrument, surgical, powered

2.1 SUBSTANTIALLY EQUIVALENT

The PASCAL Synthesis Delivery System is substantially equivalent in intended use and has the same technological characteristics as the delivery system incorporated into PASCAL Photocoagulator (K043486). The PASCAL Synthesis Delivery System is also substantially equivalent to the Infinitech Multi-Spot Slit Lamp Laser Adapter (K971950) by Infinitech, Inc. in functionality and technology in that when this device is connected to another laser, it enables the user to perform multi-spot laser photocoagulation.

2.2 DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The PASCAL Synthesis Delivery System is a scanning laser delivery system that enables the use of proprietary pattern scanning technology of the PASCAL multi-spot photocoagulator (a predicate device) with other commercially available laser platforms. This offers existing commercially available laser platforms the ability to deliver a full spectrum of pattern scanning options. The PASCAL Synthesis Delivery System is intended for use by trained ophthalmologists for diagnosis and treatment of ocular pathology.

The PASCAL Synthesis Delivery System consists of the following system components:

1) Scanning laser delivery system integrated into an Optimedica slit lamp with LCD/Touchscreen GUI that can be positioned by the user for optimal access and viewing.
2) Scanner control module with scanner controls, power supply, electronics, optical fiber & electrical connections integrated into a slit lamp table.

The PASCAL Synthesis Delivery System is compatible with the following commercially available laser systems:

- Alcon Ophthalas 532 Eyelite Laser Photocoagulator
- Zeiss Visulas 532s

2.3 INDICATION FOR USE

The PASCAL Synthesis Delivery System is a stand alone scanning delivery system that, when connected to compatible commercially available laser photocoagulators, allows fully functional scanning Photocoagulation.

When connected to a compatible laser system, the PASCAL Synthesis Delivery System is indicated for use in the treatment of ocular pathology in both the posterior and anterior segments, retinal photocoagulation, pan retinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- Proliferative and nonproliferative diabetic retinopathy
- Macular edema
- Choroidal neovascularization
- Branch and central retinal vein occlusion
- Age-related macular degeneration
- Lattice degeneration
- Retinal tears and detachments
- Iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

2.4 CONTRAINDICATIONS

Laser surgery is contraindicated when an appropriate procedure cannot be performed safely. This occurs when tissue targets cannot be visualized properly. Under such circumstances, an important tissue structure adjacent to a target tissue might be photocoagulated inadvertently. Corneal opacities, cataract formation, and vitreous hemorrhage can all interfere with the laser surgeon's view of appropriate target structures. Treatment should be delayed until visualization has adequately improved.

2.5 TECHNICAL CHARACTERISTICS

All user parameters and technological characteristics of the PASCAL Synthesis Delivery System are consistent with those of the predicate device, the OptiMedica PASCAL Photocoagulator. Specifically, the PASCAL Synthesis Delivery System is the same delivery system as the delivery system in the cleared PASCAL Photocoagulator (K043486). Both delivery systems utilize a scanner to enable faster retinal photocoagulation. Both devices may operate in an equivalent Single Spot Mode as well as in a Pattern Mode, where the aim beam is rapidly scanned allowing the physician to visualize a user-selected pattern of spots at the appropriate location for treatment. Similar to the second predicate device, the Infinitech Multi-Spot laser adapter, the PASCAL

Synthesis Delivery System is a stand alone unit that can perform multiple spot photocoagulation when connected to a compatible external laser system. Both the PASCAL Synthesis Delivery System and the Infinitech Multi-Spot laser adapter deliver laser power from the separate 532nm laser system they are connected to. Once activated by the user, the PASCAL Synthesis Delivery System delivers a predetermined pattern by sequentially scanning the placement of the laser spots and controlling the emission of the individual pulses of laser light. Likewise, treatment may be aborted by releasing the footswitch.

The PASCAL Synthesis Delivery System has been tested and found to be compatible with the Zeiss Visulas 532s (K013402) and the Alcon Ophthalas 532 Eyelite Laser Photocoagulator (K962592) laser systems. At this time, no other systems have been tested for use with the PASCAL Synthesis Delivery System.

2.6 PERFORMANCE DATA

System performance verification testing was completed to verify that measured system performance complies with specifications and requirements. This was accomplished by connecting the PASCAL Synthesis Delivery System to the Zeiss Visulas 532s and the Alcon Ophthalas 532 Eyelite Laser Photocoagulator laser systems and performing functionality testing to verify that measured system performance complies with defined system specifications and performance requirements. This testing and evaluation was performed at OptiMedica's facility in Santa Clara CA and at outside test facilities as required.

Extensive system level testing was also completed, including system and software verification & validation testing, system life testing, system environmental & shipping testing, EMC/EMI and Electrical safety compliance testing along with system performance testing. System performance testing included evaluation of power delivered, pulse widths, scan patterns, spot size & beam uniformity. All test results demonstrated that performance of the PASCAL Synthesis Delivery System, when connected to these two commercially-available laser systems, was equivalent to the performance of the PASCAL Photocoagulator that incorporates the same delivery system. Verification testing conducted on the PASCAL Synthesis Delivery System also demonstrated compliance with system performance requirements and specifications; this testing further confirmed that this device consistently and accurately produces laser outputs that are equivalent to those produced by the PASCAL Photocoagulator predicate device.

2.7 BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The indications for use for the PASCAL Synthesis Delivery System are the same as those cleared for the predicate device, the PASCAL Photocoagulator (K043486). The materials used for the manufacture of the PASCAL Synthesis Delivery System and the delivery system of the predicate device, the PASCAL Photocoagulator, are also the same. Testing of the PASCAL Synthesis Delivery System has demonstrated that it is functionally equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 0 9 2008

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733 Bolsana Drive
Laguna Beach, California 92651

Re: K081744
Trade/Device Name: PASCAL Synthesis™ Delivery System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 18, 2008
Received: June 19, 2008

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081744

Device Name: PASCAL Synthesis™ Delivery System

Indications for Use:

The PASCAL Synthesis Delivery System is a stand alone scanning delivery system that, when connected to compatible commercially available laser photocoagulators, allows fully functional scanning photocoagulation.

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- Iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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